

Understanding Ethical Issues of Research Participation from the Perspective of Participating Children and Adolescents: A Systematic Review

Additional Materials for Online Publication Only

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Table S1

Articles Included in Sample: Summary and Characteristics

Citation	Purpose / Aims	Overall Findings / Conclusions	Country	Journal
(Bagley et al., 2007)	To evaluate factors that would influence children and adolescents' decision-making for research participation, in terms of the impact of monetary and other incentives.	An age-appropriate token of appreciation as an inducement for research participation is appropriate for the younger child who is < 9 years old, because they generally have an inadequate understanding of the value of money and, therefore, the meaning of a wage. A wage-payment model for compensating older children (>9 years of age) and adolescents for the time and effort of research participation is appropriate because they generally understand the meaning and value of a wage.	United States	Pediatrics
(Birnie et al., 2011)	To describe the ethical challenges and acceptability of the cold pressor test from the perspective of researchers, children and parents.	The majority of researchers, children, and parents reported positive experiences with the CPT. The cold pressor test was judged by researchers, children, and parents to be an acceptable research method. The cold pressor test can be used ethically in pediatric research with appropriate study safeguards.	Canada	Journal of Pediatric Psychology
(Brawner et al., 2013)	To determine adolescents' perceptions of participation in research involving the collection of biomarkers via blood, saliva and/or urine samples.	Participants had favourable attitudes toward biobehavioural research and were amenable to provide each specimen type. Mistrust for research emerged, however, and concerns related to privacy and confidentiality were expressed. This paper provides a context for the research participants' decision-making process, strategies to allay fears and concerns and concrete areas to target in research-related interventions.	United States	Annals of Human Biology
(Bruzese & Fisher, 2003)	To examine the capacity of 4th, 7th, and 10th graders, as well as college students, to understand their rights in research and the extent to which this capacity can be enhanced following exposure to The Research Participants' Bill of Rights.	Fourth graders performed poorer than older respondents when asked to match rights definitions, identify true and false statements about specific research rights, and label and recognize rights violations in hypothetical research vignettes. Data suggest that 7th graders, when compared to older participants, are still struggling to understand their veto power over adult permission, their right to be protected from harm, and to be informed about research procedures and results. Overall, 10th graders' responses did not differ from adults'.	United States	Applied Developmental Science
(Burke et al., 2005)	To maximize the amount of information children and adolescents understand about the risks and benefits associated with participation in a biomedical research study.	By creating age appropriate modules of information, children as young as six years can understand potentially difficult and complex concepts such as the risks and benefits associated with participation in biomedical research. It appears, however, that different criteria were used by children in determining treatment preference, regardless of associated risks; older participants tended to opt for mobility whereas younger participants stayed with the more familiar procedure.	Canada	Journal of Medical Ethics

Citation	Purpose / Aims	Overall Findings / Conclusions	Country	Journal
(Chu et al., 2008)	To compare the effects of research participation on children who have experienced traumatic events with children who have not, in their perception of the risks and benefits of research participation and their understanding of assenting to participate.	Children's perceptions of costs and benefits of research participation and understanding of informed consent did not vary as a function of trauma exposure. The number of traumatic events experienced was unrelated to children's perceptions. Furthermore, children across trauma-exposure groups generally reported a positive cost-benefit ratio and understanding of the consent information.	United States	Journal of Empirical Research on Human Research Ethics
(Cohn et al., 2005)	To explore the factors that influenced adolescents' decisions to participate in an ED-based research study about youth violence, and to determine the feelings elicited by being a research subject.	The majority of subjects perceived their decision to participate to be free of coercion, and few felt badly about having participated. However, adolescents who were alone in the room during the assent process were more likely to report that they chose freely to be a research subject.	United States	American Journal of Bioethics
(Ellonen & Pösö, 2011)	To evaluate children's perceptions of completing a research survey about their exposure to violence.	The most vulnerable group of children, those who had experienced most serious violence, described the survey both in negative and positive terms. Their message was that the survey made some of them feel anxious, bored or confused, and others described it as therapeutic and empowering. All in all, researchers claim that children should not be excluded from research concerning sensitive research topics due to ethical reasons, but rather that different kinds of sophisticated practices should be developed to meet the needs and rights of children.	Finland	Children & Society
(Ensign, 2006)	To describe the experiences and perspectives of homeless young people as participants in research, including their perspectives and advice on how to handle ethical challenges posed by such research.	The majority of young people reported positive experiences as research participants in the past. None reported coercive research experiences; however, many stated that they would have liked more information about how the data they provided would be used by the researchers. All participants reported that it was important to be provided with research incentives, and thought that small monetary or pre-paid phone cards were appropriate incentives. They did express concerns that larger research incentives could be coercive and harmful for some homeless young people.	United States	Journal of Advanced Nursing
(Fernandez et al., 2009)	To define an appropriate process for providing research results to participants in pediatric oncology clinical trials, based on participants' needs and attitudes.	Parents of children with cancer and adolescents with cancer feel strongly that they have a right to be offered research results and have specific preferences of how and what information should be communicated based on whether results are positive or negative. Most wanted the summary to include long-term sequela and suggestions for participants, effect on future treatments, and subsequent research steps. Understanding the researcher was a main concern about receiving results.	Canada and United States	Journal of Clinical Oncology

Citation	Purpose / Aims	Overall Findings / Conclusions	Country	Journal
(Fisher, 2003)	To empirically examine generational and ethnic variations about ethical issues in youth drug use and suicide survey research in order to: a) evaluate risks and benefits, b) establish guardian permission requirements, c) develop disclosure and confidentiality policies, and d) identify appropriate incentives for recruitment.	The value of survey research for understanding, preventing, and treating adolescent drug use and self-harm behaviors rests in part on ethical procedures that provide scientifically sound responses and that merit participant trust. The ability to meet these dual obligations can be enhanced through careful consideration of the expectations, fears, and hopes with which adolescents and their parents approach youth risk surveys. Results suggest that adolescents and parents are sympathetic to the ethical dilemmas underlying decisions to waive parental permission for surveys on youth, and to the ambiguities tied to confidentiality and disclosure policies for adolescent drug use and suicide survey research. The most appropriate policies will emerge from a dialectical exchange between investigators and communities.	United States	Ethics & Behavior
(Langhinrichsen-Rohling et al., 2006)	To examine distress related to answering personal survey questions about drug use, suicidal behavior, and physical and sexual abuse in multiple convenience samples of adolescents.	Results indicated that small percentages of adolescents in every sample reported frequently feeling upset while completing the survey. Age, race, gender, and data collection strategy did not emerge as significant predictors of feeling upset. Instead, adolescents reporting a history of suicidal ideation or attempt, illicit drug use, or experiences of physical or sexual victimization endorsed more frequent feelings of upset while completing the survey than peers without these experiences.	United States	Violence & Victims
(Mayeux et al., 2007)	To investigate children's and teachers' perceptions of emotional responses to sociometric testing, and whether children understood their research rights as participants. Also to measure both quantitative and qualitative aspects of the sociometric experience.	Results indicate that children were not hurt or upset by the testing, most enjoyed the procedures, did not feel that their peers treated them any differently following the testing, and understood their research rights. There were no relations between social preference as determined by peer nominations and teacher- and self-reported responses to sociometric testing.	United States	Merrill-Palmer Quarterly
(Moreno et al., 2012)	To determine older adolescents' responses after learning that they were participants in a research study that involved identification of participants using Facebook.	The majority of adolescent participants viewed the use of Facebook for research positively. Among participants who were uneasy or concerned, the majority voiced confusion regarding their current profile security settings.	United States	Journal of Adolescent Health
(O'Reilly et al., 2012)	To explore parent and children's views of anonymity and the intrinsic link to the ethic of confidentiality with the objective of questioning the taken-for-granted nature of the ethic of anonymity.	While it is clear that anonymity remains a complex issue with participants still requiring a research framework which protects them from possible harm, the issue of anonymity may need to be further explored. In this research study, both children and adults were interviewed, and while the adults could be afforded choice regarding identification, children chose to be protected from identification.	United Kingdom	International Journal of Social Research Methodology

Citation	Purpose / Aims	Overall Findings / Conclusions	Country	Journal
(Reynolds & Nelson, 2007)	To increase our understanding of how diabetic and at-risk adolescents (i.e., those who are obese and/or have a family history of diabetes) and their parents perceive risks and make decisions about research participation.	Results suggest that parents' and adolescents' research risk perception and decision making for participation in hypothetical diabetes-related research procedures is influenced by subjective factors. The intent of informed consent is to protect patients by ensuring that they understand important information about the research study. However, the affect heuristic and priority heuristic enable decision making without requiring one to assess all available information. Researchers may find it difficult to assess the extent to which their research participants understand the risks of study participation when those participants employ affective and other heuristic processes to evaluate risk information.	United States	Social Science & Medicine
(Swartling et al., 2011)	To explore what views children 10–12 years of age express about medical research and participation in such research.	The study concludes that the children feel positive towards medical research, and want to take an active part in decisions and have their integrity respected. However, the study also indicates that children who had participated in a longitudinal screening research study had a limited understanding of this study, suggesting the vital importance of providing information appropriate to their age and maturity. This information should be provided out of respect for the children as persons, and to promote continued participation in longitudinal studies.	Sweden	Journal of Empirical Research on Human Research Ethics
(Swartling et al., 2014)	To explore 10- to 13-year-old children's views on medical research, trust, information, decision making, and their views on data sampling and risk identification.	The results show that children 10 to 13 years of age have in general a positive attitude to pediatric research and emphasized trust in researchers. The children stressed the importance to receive information and to be involved in decisions. The children also reported feeling concerned about blood sampling and disease risk. Researchers involved in long-term pediatric research need to address these issues to promote involvement and decrease worry.	Sweden	Journal of Empirical Research on Human Research Ethics
(Traube et al., 2013)	To examine factors influencing informed assent, initial involvement, and ongoing involvement in HIV-focused community based participatory research for African American children.	Children's participation was catalyzed by a motivation to help their community and a belief that they could trust the research team. Children voiced distinct opinions about whom they felt most comfortable speaking with (white researchers from outside their community). This was in opposition to statements made by African American adults engaged in HIV-focused community based participatory research who voiced preferences for research staff from their own community. Issues of informed assent were closely tied to issues of motivation to participate in research and trust.	United States	Journal of Empirical Research on Human Research Ethics
(Unguru et al., 2010)	To assess what children aged 7 to 18 with cancer understand about research, their research-related treatment, and their preferences for inclusion in decision-making.	Most children have limited understanding of research despite physicians' explanations. Many children reported that they feel minimally involved in the decision to enroll in clinical trials. Tools to assist investigators ascertain that children understand what they are agreeing to when they assent to research and to determine their preferences for inclusion in research may help make assent more meaningful.	United States	Pediatrics

Citation	Purpose / Aims	Overall Findings / Conclusions	Country	Journal
(Vitiello et al., 2007)	To examine the extent to which parents and adolescents participating in the Treatment for Adolescents With Depression Study understood key aspects of the study.	Most parents and adolescents were well-informed research participants. Difficulties in appreciating the research nature of the trial, however, emerged, especially among participants assigned to psychotherapy. Parents were overall better informed than adolescents.	United States	Journal of the American Academy of Child and Adolescent Psychiatry
(Wagner et al., 2006)	To prospectively assess youths' and their parents' attitudes and experiences about participation in clinical treatment research.	The majority of youths and parents had a positive view about their experiences of participating in clinical treatment research, independent of whether or not the youth's psychiatric condition improved. The majority of youths and parents reported that finding out about the youth's problem and receiving treatment were the main reasons for participation in the clinical treatment studies. Most youths liked their treatment, believed the study proceeded as expected, were glad to have participated in this study, and would participate in another study.	United States	Journal of Child & Adolescent Psychopharmacology
(Woodgate & Edwards, 2010)	To detail how parents as well as children view and assess the risks to involving children in health research. This paper focuses on one of the factors, a matter of trust, that shaped Canadian parents' and children's perceptions and assessments of risk in child health research.	This study reinforces that trust is an important factor when parents assess risk in child health research and shows that children use the language of trust in relation to risk. The presence or absence of trust was not only perceived by parents and children as a contributing factor to involving children in health research, but also shaped their perceptions and assessments of risk. Three interrelated subthemes identified were: (1) relationships of trust; (2) placing trust in symbols of authority; and (3) the continuum of trust.	Canada	Journal of Medical Ethics

Table S2

Articles Included in Sample: Methodologies Used

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Bagley et al., 2007)	Children were asked to participate in different research scenarios. When a child declined to participate in a hypothetical research scenario, they were asked if incentives would change their mind. Only interviews from children who declined to participate in hypothetical research scenarios were included.	Secondary analysis; Recruitment method and site(s) of primary study not discussed.	Qualitative (method not otherwise specified), Descriptive, Cross-Sectional	Unstructured interviews lasting an hour. Secondary analysis of interview transcripts from a larger study of child assent and parent permission for research.	Peabody Picture Vocabulary Test.	Four different hypothetical research scenarios were presented.	Not discussed	Assent obtained. Specifics not discussed.	Verbal parent / guardian permission obtained. Not otherwise discussed.
(Birnie et al., 2011)	Children were given a questionnaire to complete at home after concluding their participation in a study that used one or two cold pressor test(s).	Centre for Pediatric Pain Research at IWK Health Centre in Halifax, Canada.	Quantitative, Descriptive, Cross-sectional	None	Novel questionnaire with open-ended questions assessing research experience for: Enjoyment; Best and least liked things; Impact; Importance; and Would recommend to a friend.	All children had participated in one of five different studies using the cold pressor test.	None	Not discussed.	Not discussed.
(Brawner et al., 2013)	Adolescent females receiving outpatient mental health treatment completed a questionnaire and then immediately participated in a focus group.	Outpatient mental health treatment settings in Philadelphia, PA and Hampton, VA.	Mixed methods, Descriptive, Cross-sectional	Focus groups with 3 – 8 participants per group lasting 2 hours each, using a structured guide with open-ended questions. Due to poor focus group attendance, 2 adolescents were interviewed individually.	Novel questionnaire with Likert questions assessing attitudes, beliefs, willingness / intentions of research participation.	Hypothetical research scenarios were presented that involved the collection of blood, saliva, or urine sample(s).	\$20 cash	Face to face recruitment. Assent obtained. Specifics not discussed.	Verbal parent / guardian permission obtained. Not otherwise discussed.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Bruzzese & Fisher, 2003)	After consenting to this study, participant's understanding of the consent form was assessed. Participants were then read a lesson either on rights in research or the field of psychology and then completed four additional tasks to assess their understanding of research rights.	4th, 7th, and 10th grade classrooms (number and location of schools not otherwise described); Jesuit University.	Quantitative, Cross-sectional, Descriptive and Interventional	Study activities were completed individually when students were grouped together in a classroom. Questions and lesson plans were read aloud while students followed along with written materials and completed the activities. Students were encouraged to ask questions, but asked not to refer back to the lesson books.	Two novel lessons: 1) Research Participants' Bill of Rights and 2) Psychology, the Science of Human Behavior. Five novel quantitative assessments: 1) Consent Form Comprehension, 2) Rights Definition, 3) True-False, 4) Rights Violation Labeling, and 5) Rights violation awareness. Hollingshead index of Social Status. Reading Level: Stanford Achievement Test or Scholastic Aptitude Test.	This research study and 16 hypothetical research vignettes involving different risk-taking behaviors (including scenarios where rights were violated and maintained) provided the research context.	Age-appropriate incentive. Either party favors, introductory psychology course credit, or a gift certificate drawing.	Study first verbally presented. Then written assent form, study information sheets and parent permission slip provided to non-college age interested students.	Written parent / guardian permission slip used for non-college age students.
(Burke et al., 2005)	Participants were presented a hypothetical research study with an information form, and asked questions regarding their understanding of what they'd been told and read. Credit was given if the answer corresponded to a reasonable response for the question, based on information they were provided.	Outpatient waiting rooms at the Hospital for Sick Children in Toronto, Canada.	Quantitative, Cross-sectional, Descriptive and Interventional	Structured individual interviews with parents and children (occurred simultaneously in the waiting room). Participants were read verbatim the information form and encouraged to consult the study information sheet when answering questions.	Six novel study information forms. Risks and benefits associated with each of the treatment options were manipulated so that for each one of the six protocols there was either a correct or ambiguous choice.	One of six hypothetical research protocols were presented that described how to fix a fractured thigh using either a standard cast or new pins procedure.	Not discussed.	Assent obtained using a written form. Parents and children were simultaneously approached.	Written parent / guardian consent form used.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Chu et al., 2008)	Children and parents completed questionnaires assessing their perceptions of participating in research after completing all other activities involved with a study examining children's reactions to stressful events.	Community based study in urban Denver, CO	Quantitative, Cross-sectional, Descriptive	Structured individual interviews. All items were read out loud to children. Before leaving, children were told about the purpose of the study and asked to talk about a pleasant event with the researcher.	Reactions to Research Participation Questionnaire for Children. UCLA- PTSD Index. Child Dissociative Checklist. Block Design and Vocabulary scales of the Wechsler Intelligence Scales for Children. From two larger studies: tasks assessing cognitive ability and ability to understand emotion.	Participants had completed one of two research studies examining children's reaction to stressful events.	Parent-child dyads paid \$30 for study 1, and \$50 for study 2 (\$25 per session). Children received several small prizes.	Assent obtained using a written form. Understanding was assessed using a quiz. Children had to answer all quiz questions correctly.	Written parent / guardian consent form used. Understanding was assessed using a quiz. Parents had to answer all quiz questions correctly.
(Cohn et al., 2005)	After participating in a violence assessment survey study, participants were asked to answer three questions related to their participation in the research study. All participants had been injured as a result of a violent event that was not accidental or related to child abuse or domestic violence.	Emergency department at one pediatric and one adult hospital in an urban setting.	Quantitative, Cross-sectional, Descriptive	Structured, individual interviews.	Novel questionnaire with three questions that could be answered with Yes, No, or Maybe. Questionnaire assessed research experience for: Voluntariness, satisfaction, and distress.	Participants had just completed a research survey study assessing violence.	Not discussed.	Assent was obtained using a verbal script. Presence of someone else when assent was obtained was tracked.	Parent / guardian was first consented. Not otherwise discussed.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Ellonen & Pösö, 2011)	School-based survey assessing children's experiences with violence in the home and at school, conducted by the Police College of Finland.	Finnish school-aged children were surveyed during the school day. All schools were invited; principals decided whether their school would participate.	Quantitative, Cross-sectional, Descriptive	None	Novel instrument – the Finnish Child Victim survey 2008 - that included one final open-ended question asking 'how did you feel answering the questions'. Strengths and Difficulties Questionnaire , measuring emotional problems, conduct problems, hyperactivity, and social problems.	Participants had just completed a research survey study assessing their experiences with violence.	Not discussed.	Assent evidenced by students' completion of the survey. Voluntary-ness questioned as survey was part of the school day, and was conducted by teachers at each school.	Parents did not provide consent for children to participate – children decided whether to participate and parents were informed afterwards.
(Ensign, 2006)	Participants were asked to share the meaning of the term 'research', their own experiences in previous research, views regarding research consent and incentives for research, and recommendations for future research endeavors.	Two street locations known to be popular with homeless young people, and the main clinic for homeless young people in Seattle, WA.	Qualitative Focused Ethnography , Cross-sectional, Descriptive	Semi-structured individual interviews, followed by focus groups to validate and expand on initial findings.	None	Participants had some sort of prior research experience while being homeless, and shared insights from these prior experiences.	\$10 pre-paid phone card.	Verbal assent / consent was obtained.	Parent consent not obtained; waived by IRB since research was with homeless young people.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Fernandez et al., 2009)	Adolescents with cancer were identified as potential participants based on the date of their cancer diagnosis (wanted newly diagnosed patients) and were subsequently surveyed when in follow-up after their cancer treatment.	Five out-patient pediatric oncology clinics in the U.S. and Canada.	Quantitative, Cross-sectional, Descriptive	None	Novel questionnaire regarding receiving research results. The age-appropriate Positive and Negative Affect Schedule for Children (PANAS-C) or Positive and Negative Affect Schedule - Expanded Form (PANAS-X) .	Participants were asked to consider a hypothetical situation where they had taken part in a research study, and the final results of the study were either beneficial, harmful, or neutral for participants.	Unspecified token of appreciation.	Assent was presumed on return of the anonymous questionnaires. Not otherwise discussed.	Consent was presumed on return of the anonymous questionnaires. Not otherwise discussed.
(Fisher, 2003)	Adolescents and their parents completed a survey on either drug use research or suicide research.	Four New York City schools.	Quantitative, Cross-sectional, Descriptive	None	Ethics for Adolescent Research Questionnaire – a novel instrument using a Likert scale.	Participants were asked to share their overall impression of research on drug use and suicide.	Movie theater gift certificate.	Assent obtained using a written form.	Written parent / guardian consent form used.
(Langhinrichsen-Rohling et al., 2006)	After participating in a survey study about drug use, suicide, and physical and sexual abuse, participants were asked to answer two questions related to their completion of the survey.	Four different settings in the U.S. southeast were used to recruit participants- a high school, a middle school, a juvenile justice truancy program, and the juvenile justice probation system.	Quantitative, Cross-sectional, Descriptive	None	History of Sensitive Events (History of suicidal behavior, physical or sexual abuse, or drug use) using dichotomous questions. Novel survey impact measure using a Likert scale; with one question on psychological distress and another on interest in survey.	Participants had just completed a research survey study assessing their experiences with drug use, suicide, and physical and sexual abuse.	None for sample from High school, Candy for sample from Middle school, \$10 for sample from Truancy and Probation programs. \$1 was given directly to the middle and high school per participant recruited	Assent was obtained from all participants. Not otherwise discussed.	Written parent consent (Middle school and Probation programs), Parent sent opt-out letter (High school), Verbal parent consent (Truancy program).

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Mayeux et al., 2007)	After participating in a research study at school involving sociometric testing, children were asked to answer questions related to their experiences with the sociometric testing. The sociometric testing was a peer nomination instrument that asked children to nominate peers in terms of 'liked least', 'liked most', etc. The sociometric testing listed all children in the classroom; even non-consenting children were open to nomination by their peers.	Five elementary public schools in a suburb of a large urban center.	Quantitative, Cross-sectional, Descriptive	One hour structured interview was conducted as part of a larger longitudinal study. The Classroom Testing Survey was administered during this interview. The interview was conducted between 7 to 31 weeks after the sociometric research study.	Novel questionnaire – the Classroom Testing Survey – using Likert scale questions to assess children's reactions to the sociometric testing, treatment by peers following testing, understanding of research rights, and overall reactions.	All children had participated in the same sociometric research study.	\$25 cash at the end of the one hour interview for the larger longitudinal study.	Written assent was obtained from all participants, following parent consent to participate.	Active parent consent obtained. Not otherwise discussed.
(Moreno et al., 2012)	After participating in a research study the health of college students, participants were asked to answer a question about how they were recruited to the study.	Publicly available Facebook profiles of freshmen undergraduate students within one large state university Facebook network.	Qualitative (not otherwise specified), Cross-sectional, Descriptive	Semi-structured individual interview. Length not specified.	One open-ended question was asked: Do you have any thoughts about the use of publicly available Facebook profiles to recruit participants to this study?	All participants had been recruited via Facebook and had just completed a research study about college student health.	\$50	Details of method for obtaining participant consent were not discussed.	Not applicable.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(O'Reilly et al., 2012)	As part of a larger researcher study into children's educational needs, interviews were carried out with children who experienced educational and mental health difficulties, and specific questions related to confidentiality and anonymity were asked at the end of the interview.	Parents and children linked with Child and Adolescent Mental Health Services were recruited to participate.	Qualitative – Discourse Analysis, Cross-sectional, Descriptive	Individual semi-structured interviews. Whenever possible children were interviewed alone.	None	Participants had just completed a qualitative research study into children's educational needs.	Not discussed.	Not discussed.	Not discussed.
(Reynolds & Nelson, 2007)	For three different research procedures, participants read a procedure description and then were asked a series of questions about their understanding of the procedure, its risks, benefits, and any other observations. They then read information about the procedure risks and were prompted to discuss their perceptions of these risks and their decision whether to undergo the procedure. Participants were then asked to compare risks they perceived in their everyday lives to the risks of research participation.	Endocrinology departments of two north-eastern U.S. hospitals and through referrals from other researchers .	Qualitative (not otherwise specified), Cross-sectional, Descriptive	Structured, individual interviews lasting between 40 and 75 minutes.	Novel interview guide was developed for this study based on consent and assent documents used in studies employing one or more of the three procedures.	Participants were presented three hypothetical research procedures, and asked to consider the risks of research participation .	\$20	Not discussed.	Not discussed.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Swartling et al., 2011)	Current All Babies in Sweden research study participants at the 10-12 year follow-up time point and a new 10-12 year control group established for the All Babies in Sweden research study were asked to participate in a focus group about medical research.	School based study in Sweden.	Qualitative (not otherwise specified), Cross-sectional, Descriptive	Focus groups using a free-association narrative interview method.	None	Participants were asked to share their overall impression of research. Only some children had participated in the All Babies in Sweden research study.	Not discussed.	Child's assent obtained. Details not discussed.	Parental consent obtained. Details not discussed.
(Swartling et al., 2014)	Current All Babies in Sweden research study participants at the 10-12 year follow-up time point and a new 10-12 year control group established for the All Babies in Sweden research study were asked to complete a questionnaire about their feelings regarding the study.	School based study in Sweden.	Qualitative (not otherwise specified), Cross-sectional, Descriptive	None	Novel instrument using Likert scales to assess views on pediatric research, information, and decision-making, as well the child's feelings regarding this research study.	All children were participating in the All Babies in Sweden research study.	Not discussed.	Child's assent obtained. Details not discussed.	Parent received an opt-out letter for their child (children brought it home with them).
(Traube et al., 2013)	After being enrolled but prior to their participation in the Chicago HIV and Adolescent Mental health Project study, participants were interviewed to assess factors that influence the extent to which children are knowledgeable about the purpose of the study, clear about the expectations associated with participation, and accurate about the risks and benefits.	Schools adjacent to or in public housing projects in Chicago.	Mixed methods, Cross-sectional, Descriptive	Structured individual interviews lasting 45-60 minutes. Interviews occurred after school hours at the school. Interviews were conducted by trained African American members of the community.	Novel interview guide developed from the Research Information Questionnaire , using a combination of Likert scale and open-ended questions.	All children were enrolled in the Chicago HIV and Adolescent Mental health Project, a family-based HIV prevention study.	\$10	Child's assent obtained. Details not discussed.	Parental consent obtained. Details not discussed.

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Unguru et al., 2010)	Children who participated in a pediatric oncology clinical trial were asked questions to assess their understanding about research, their research-related treatment, and their decision-making preferences.	Pediatric oncology clinic at Children's National Medical Center.	Quantitative, Cross-sectional, Descriptive	Structured, individual, private interviews. Children followed again while all questions were read aloud.	Novel instrument – Quality of Assent – using a combination of 69 open- and closed-ended questions.	All children were participating or had previously participated in a pediatric oncology clinical trial.	Not discussed.	Child's written assent obtained, with the children's parents present.	Parental written consent obtained.
(Vitiello et al., 2007)	Children who participated in the Treatment for Adolescents With Depression Study completed a self-administered multiple choice test at the week 6 treatment visit to assess their understanding of the study.	Thirteen outpatient adolescent mental health treatment centers across the U.S.	Quantitative, Cross-sectional, Descriptive	None	Novel instrument using multiple choice questions to assess understanding of the research study, their research rights, and their motivation for participation.	All children were participating in the Treatment for Adolescents With Depression Study.	None	Child's written assent obtained. Flesch Reading Ease Score was 63.9 and the Flesch-Kincaid Grade level score was 8.5 for the assent form. Parent was present when assent was obtained.	Parental written consent obtained.
(Wagner et al., 2006)	Children completed questionnaires pre-study (prior to enrolling in the clinical treatment research) and post-study (at the end of the clinical treatment study).	A large, out-patient, academic medical center.	Quantitative, Descriptive, Longitudinal, Pre/post questionnaire study	None	Novel instrument assessing reasons for enrolling in the study, the informed consent process, views and placebo (if applicable), and expectations about improvement and quality of care during the treatment study. Clinical Global Impressions—Severity score and Improvement score.	All children had participated in one of several different outpatient pediatric psychopharmacology treatment studies.	Not discussed.	Child verbal assent obtained (written assent was obtained for treatment study).	Parent verbal consent obtained (written consent was obtained for treatment study).

Citation	Approach	Site(s)	Method	Interviewing Technique	Instruments	Research Context	Use of Incentives	Child / Adolescent Method of Assent	Parent Method of Consent
(Woodgate & Edwards, 2010)	Children were interviewed regarding their perceptions of risk in research studies involving children.	Community-based study in a Western Canadian city. Participants were recruited through a community newsletter, or a letter from a clinic, day care center, or day camp.	Qualitative - Grounded theory, Descriptive	In-depth qualitative, open-ended, individual interview lasting from 30 to 180 minutes. Three focus group interviews were conducted near the end of the study with some of the children who had previously been interviewed.	Novel interview guide intended to help draw out participants' thoughts, feelings and experiences about risk and children in research.	Participants were asked to share their overall thoughts on perceptions of risk in research studies involving children.	Not discussed.	Child's assent obtained. Details not discussed.	Parent's consent obtained. Details not discussed.

Table S3

Articles Included in Sample: Demographics of Participating Children and Adolescents

Citation	Health	Research Experience	Ages	Sample Size	Race / Ethnicity	Recruitment Rate
(Bagley et al., 2007)	Combination of children with diabetes, asthma, seizures, and healthy children	Not discussed	4 – 16 years	n=42	Not discussed	Not discussed
(Birnie et al., 2011)	Combination of healthy children and children with a history of headache or abdominal pain	Some children had other research experience prior to the cold pressor study, others did not	7 – 17 years	n=175	Not discussed	70.3% N=249
(Brawner et al., 2013)	Adolescent females receiving outpatient mental health treatment	Some participants (65%) had previous research experience, others did not	12 – 19 years	n=37	African American (73%), Mixed race / ethnicity (24%), Native (3%)	Not discussed
(Bruzzeze & Fisher, 2003)	Participants were recruited from educational settings. Sample health not discussed.	Not discussed	8-10, 14-17, 17-27 years	n=291 82-4 th grade, 63-7 th grade, 75-10 th grade, and 71 college students	White (73%), Hispanic (16%), Asian (4%), Other (7%)	65% in 4 th grade, 52% in 7 th grade, and 64% in 10 th grade students Not tracked in college students
(Burke et al., 2005)	Participants were recruited from outpatient waiting rooms in a large pediatric hospital. Sample health not discussed.	Not discussed	6 – 15 years	n=251	Not discussed	Not discussed
(Chu et al., 2008)	Children exposed to interpersonal trauma events (38%), children exposed to non-interpersonal trauma events (34%), and children not exposed to trauma events (28%). No other health information discussed.	Not discussed	7-12 years	n=181	39% Euro-American, 25% African-American, 23% Hispanic / Latino, 3% Native American, 2% Pacific Islander, 8% Other or Multiracial	Not discussed

Citation	Health	Research Experience	Ages	Sample Size	Race / Ethnicity	Recruitment Rate
(Cohn et al., 2005)	All participants had been injured as a result of a violent event that was not accidental or related to child abuse or domestic violence, but were not too ill to answer research questions.	Not discussed	11-19 years	n=70	86% African American, 1% White, 3% Other, 10% Unknown	74% N=94
(Ellonen & Pösö, 2011)	Not discussed	Not discussed	6 th grade students (12-13 years) and 9 th grade students (15-16 years)	n= 13,459	Not discussed	12% of schools did not participate per decision of the principal 15% of children did not respond to the research experience question
(Ensign, 2006)	Not discussed	Not discussed	15-23 years	n=30 individual interviews, n=13 focus group participants	Not discussed	Not discussed
(Fernandez et al., 2009)	All adolescent participants had been treated for cancer and were in a follow-up period.	50% had previous research experience, 37% did not have previous research experience, 9% didn't know if they had research experience	12-22 years	n=112	White 79.1%, Asian 4.4%, African American 5.8%, Latin 1.1%, Middle Eastern 2.3%, Other /Unknown 3.5%	60.5% N=185
(Fisher, 2003)	Not discussed	Not discussed	7 th – 12 th graders students (ages not specified)	n=322	African American 17%, Hispanic 19%, East Asian 18%, South Asian 2%, Multi-racial 16%, Other 4%	Not discussed
(Langhinrichsen-Rohling et al., 2006)	Not discussed	Not discussed	13-18 years	n= 1,540	37.7% White, 49.8% African American, 1.9% Hispanic, 2.3% Asian, 2.5% Native, 5.8% Other	62% Middle school, 93% High school, 67% Truancy program, 69% Probation

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(Mayeux et al., 2007)	Not discussed	Not discussed	3 rd grade students (ages not specified)	n=96	42.4% White, 24.3% African American, 24.0% Hispanic, 8.9% Asian	43% N=218
(Moreno et al., 2012)	Not discussed	Not discussed	18-19 years	n=132	91.7% White, 3.8% Asian, 3.1% Hispanic, 0.7% African American, 0.7% Mixed race	N=188
(O'Reilly et al., 2012)	All participating children had mental health problems and educational difficulties	Not discussed	8-10 years	n=11	Children were from multiple ethnic backgrounds. Details not discussed.	Not discussed
(Reynolds & Nelson, 2007)	15 participants had diabetes; 17 participants were overweight / at risk for developing diabetes	15.6% of adolescents were participating in a research study that used two of the hypothetical research procedures	12-17 years	n=32	34.4% African American, 59.4% White, 6.2% Other	Not discussed
(Swartling et al., 2011)	Not discussed	Not discussed	10-12 years	n=39	Not discussed	Not discussed
(Swartling et al., 2014)	Not discussed	72% had previously participated in All Babies in Sweden study; 28% had not	10-13 years	n= 5,851	Not discussed	Not discussed
(Traube et al., 2013)	Not discussed	Not discussed	9-11 years	n=170	100% African American	62% N=274
(Unguru et al., 2010)	All children had been diagnosed with cancer	All children were participating / had participated in a pediatric oncology clinical trial	7-18 years	n=37	Not discussed	60% N=62
(Vitiello et al., 2007)	All children had been diagnosed with major depressive disorder	All children were participating in the Treatment for Adolescents with Depression Study	12-17 years	n=295	74.2% White, 10.5% African American, 10.5% Hispanic	67% N=439
(Wagner et al., 2006)	All children had been diagnosed with a psychiatric disorder	All children were participating in a psychopharmacology treatment research study	6-17 years	n=90	72% White, 16% Hispanic, 10% African American	Not discussed
(Woodgate & Edwards, 2010)	49% of children were reported to have some sort of a health problem or condition	Two groups were enrolled: children with (62%) and without (38%) health research experience	6-19 years	n=82	Not discussed	Not discussed